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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,042	11/30/2001	Hermona Soreq	1567/66364/JPW/FHB	6063
7590	06/25/2004			
Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036				
EXAMINER CHISM, BILLY D				
ART UNIT		PAPER NUMBER		

1654

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/998,042

Applicant(s)

SOREQ ET AL.

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-65 is/are pending in the application.
- 4a) Of the above claim(s) 11-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1654

### **DETAILED ACTION**

This Office Action is in response to Applicants' paper filed 04 April 2004, wherein claim 4 is cancelled and claims 18-65 are withdrawn from consideration.

Applicants stated continued traversal of the restriction requirement filed 25 July 2003, however, the traversal was not persuasive and the restriction held FINAL in the office action filed 03 December 2003. The Examiner would like to reiterate that the restriction was made FINAL in the previous office action for the reasons therein identified, as well as was identified in the restriction requirement filed 25 July 2003. Thus, the restriction remains FINAL for those reasons previously presented.

Claims 11-17 are withdrawn from consideration as being drawn to non-elected subject matter. The products and methods of making and using those products were restricted in the paper filed 25 July 2003. Applicants elected the inventive Group I, claims 1-17, drawn to a regulatory peptide. Presently, Applicants have amended previously elected products claims 11-17 to now be drawn to methods of using the previously elected product of the inventive Group I. Therefore, as claims 11-17 are now drawn to non-elected subject matter, the claims 11-17 are withdrawn from consideration.

### **Withdrawal of Objections and Rejections**

The rejections and/or objections made in the prior office action mailed 03 December 2003, which are not explicitly stated below, in original or modified form are WITHDRAWN.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 07 April 2004 will be addressed to the extent that they pertain to the present grounds of rejection.

***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1, 3 and 5-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 and those claims that are dependent on the subject thereof lack utility wherein there is no indication that the “regulatory peptide comprising” SEQ ID NO: 1 is not naturally occurring, i.e., an in vivo product of natural biochemical pathways. Applicants may obviate this rejection by amending the claim to read “An isolated regulatory peptide”, wherein it would indicate the hand of man.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2-3 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a “written description” rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

*Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., synthetic peptides comprising SEQ ID NO: 1 *and deletions, additions and substitutions thereof*. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are no specifically indicated species of the claimed genus disclosed that are within the scope of the claimed genus, i.e. peptides that are variants of SEQ ID NO: 1 as defined by disclosed specific deletions, substitutions and additions. The disclosure of one or two species

Art Unit: 1654

may provide an adequate written description of a genus when the species disclosed are representative of the genus. However, the present claims encompasses numerous species that are not further described. There is substantial variability among the numerously possible species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus comprising synthetic peptides comprising variants of SEQ ID NO: 1 *by deletions, additions and substitutions thereof*. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (see *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the term “derived from” are unclear. It is unclear the nature and number of steps required to obtain a regulatory peptide “derivative” from the C-terminal region of the read through variant of acetylcholinesterase. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the regulatory peptide as claimed from the source that it is “derived from”.

Claims 2-3 and 5-10 are rejected for depending from rejected claims.

Art Unit: 1654

*Conclusion*

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism

22 June 2004



CHRISTOPHER R. TATE  
PRIMARY EXAMINER